DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 5, 2014

Mr. Phillip Michael Lester
Regulatory Affairs Specialist
Terumo Medical Corporation
950 Elkton Boulevard
ELKTON MD 21921

Re: K140516
Trade/Device Name: Terumo® Pen Injector Needle 34
Regulation Number: 21 CFR 880.5570
Regulation Name: Needle, Hypodermic, Single Lumen
Regulatory Class: II
Product Code: FMI
Dated: July 8, 2014
Received: July 9, 2014

Dear Mr. Lester:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140516

Device Name
The Terumo® Pen Injector Needle 34

Indications for Use *(Describe)*
The Terumo® Pen Injector Needle 34 is intended for use with a pen injector device for the subcutaneous injection of drugs, including insulin.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman -S
Date: 2014.08.01 14:09:47 -04'00'

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SECTION 5 – 510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

PAGE

510(k) SUMMARY K140516

A. SUBMITTER INFORMATION (807.92(a)(1))

Prepared by: Phillip Michael Lester
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Prepared for: ***Owner/Operator***
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Date prepared: April 4, 2014

B. DEVICE NAME (807.92(a)(2))

Proprietary Name:	Terumo® Pen Injector Needle 34 (or similar)
Common Name:	Hypodermic single lumen needle
Classification Name:	Needle, Hypodermic, Single Lumen
Classification Panel:	General Hospital
Regulation:	21 CFR 880.5570
Product Code:	FMI
Classification:	Class II

C. PREDICATE DEVICE (807.92(a)(3))

The legally marketed device(s) to which substantial equivalence is claimed is/are:

1. K123300 BD 31G and 32G Extra Thin Wall (XTW) Pen Needles with PentaPoint™, manufactured by Becton, Dickinson and Company, New Jersey.
2. K052561 Terumo® Micro Tapered Pen Needle, manufactured by Kofu Factory of Terumo Corporation, Japan.

D. REASON FOR 510(K) SUBMISSION

This 510(k) is being submitted due to design modifications to the previously cleared device (K052561) that would prompt a new submission: 1) new needle gauge size, 34G (0.18 mm); 2) new needle insertion length of 4 mm (from previous 5 mm, cleared under K052561); 3) change in sterilization method (from gamma to electron beam); and 4) a change in the indications for use from the previously cleared device. Therefore, this Traditional 510(k) is being submitted for modifications to the current device (K052561) that do not qualify for Special 510(k).

E. DEVICE DESCRIPTION (807.92(a)(4))

The Terumo® Pen Injector Needle 34 is comprised of a double-tapered stainless steel needle cannula that is pointed at both the cartridge interface end, to puncture the cartridge for drug delivery, and the patient interface end, for injection into the patient's body tissue. The patient interface end features a 3-bevel, asymmetrical needle edge.

The cannula tapers from a 29G (0.33 mm) outer diameter at the cartridge interface

end to a 34G (0.18 mm) outer diameter at the needle tip (patient interface end). It is normal-walled (min. 0.089 mm inner diameter) at the needle tip, and the internal diameter tapers like the outer diameter (wall thickness is uniform throughout the needle length). The double-pointed needle is attached to a plastic hub which screws on to a compatible pen injector (not supplied with this device).

The needle insertion length (from the glue mount on the hub to the tip of the patient interface end) is 4 mm (5/32”). The length of the needle cartridge side is 6.5 mm (1/4”). The patient interface end (needle tip) is covered by a white plastic needle protector cap (inner needle cap) which is then covered by a clear plastic outer case (outer needle case). The cartridge interface end is then covered with a sealing film.

Just prior to use, the outer needle case is removed and retained for recapping once the injection is completed. The inner needle cap is then removed to expose the needle and the injection administered. After the injection, the user inserts the used needle into the open end of the outer needle case so it can be safely removed from the pen injector and disposed of immediately.

This pen needle device is individually packaged and sterilized by electron beam. It is a manually operated, disposable device intended for single use only.

F. INTENDED USE (807.92(a)(5))

The Terumo® Pen Injector Needle 34 is intended for use with a pen injector device for the subcutaneous injection of drugs, including insulin.

G. SUBSTANTIAL EQUIVALENCE COMPARISON (807.92(a)(6))

The Terumo® Pen Injector Needle 34, subject of this Traditional 510(k), is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to:

1. K123300 BD 31G and 32G Extra Thin Wall (XTW) Pen Needles with PentaPoint™, manufactured by Becton, Dickinson and Company, New Jersey.
2. K052561 Terumo® Micro Tapered Pen Needle, manufactured by Kofu Factory of Terumo Corporation, Japan.

A comparison of the intended use/indications for use and technological characteristics is summarized in the table on the following page. The minor differences of indications for use and the technological differences do not impact the safety and effectiveness of the device.

Note: A statement of substantial equivalence to another product is required by 21CFR807.87, and relates only to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is, therefore, not related to the coverage of any patent, and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the Commissioner of the FDA has stated, "…a determination of substantial equivalence under the federal Food, Drug, and Cosmetic Act relates to the fact that the product can lawfully be marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatever on the resolution of patent infringement suits" 42 Fed. Reg. 42,520, et seq. (1977)

Device Characteristic	**New Device:** Terumo® Pen Injector Needle 34	**Predicate:** TERUMO® Micro Tapered Pen Needle (K052561)	**Predicate:** BD 31G and 32G Extra Thin Wall (XTW) Pen Needles with PentaPoint™ (K123300)
Manufacturer	Kofu Factory of Terumo Corporation	Kofu Factory of Terumo Corporation	Becton, Dickinson and Company
Intended Use	The Terumo® Pen Injector Needle 34 is intended for use with a pen injector device for the subcutaneous injection of drugs, including insulin.	The TERUMO® Micro tapered pen needle is intended for use with a pen injector device for the subcutaneous injection of insulin. It is indicated for general use and for pediatric patients.	BD Pen Needle is intended for use with pen injector device for subcutaneous injection of drugs, including insulin and exenatide.
Operation Principle	Manual	Manual	Manual
Design / Construction	• Needle assembly (cannula, needle hub, protector cap) • Designed to fit specified pen injectors (new ISO 11608-2:2012 compatibility requirements)	• Needle assembly (cannula, needle hub, protector cap) • Designed to fit Type A pen injectors (ISO 11608-2:2000)	• Needle assembly (cannula, needle hub, protector cap) • Designed to fit Type A pen injectors
Materials	• Cannula – Stainless Steel • Lubricant – Silicone Oil • Adhesive – Polyacrylate • Needle Hub – Polypropylene • Protector Cap – Polyethylene • Outer Case – Polypropylene • Sealing Film – Kraft Paper	• Cannula – Stainless Steel • Lubricant – Silicone Oil • Adhesive – Polyacrylate • Needle Hub – Polypropylene • Protector Cap – Polyethylene • Outer Case – Polypropylene • Sealing Film – Kraft Paper	• Cannula – Stainless Steel • Lubricant – Silicone Based *Note: this is the information publicly available for the device.*
Package	• Plastic outer case • Sealing Film • Shelf box	• Plastic outer case • Sealing Film • Shelf box	• Plastic outer case • Sealing Film • Shelf box

Device Characteristic		**New Device:** Terumo® Pen Injector Needle 34	**Predicate:** TERUMO® Micro Tapered Pen Needle (K052561)	**Predicate:** BD 31G and 32G Extra Thin Wall (XTW) Pen Needles with PentaPoint™ (K123300)
Specifications	***Taper***	Double Tapered Design; 29G (0.33 mm) O.D. > 34G (0.18 mm) O.D.	Double Tapered Design; 28G (0.35 mm) O.D. > 33G (0.20 mm) O.D.	None; remains straight throughout
	Needle Length	4 mm (5/32") – Patient Interface 6.5 mm (1/4") – Cartridge Interface	5 mm (3/16") – Patient Interface 5.5 mm (7/32") – Cartridge Interface	4mm for 32G; 5mm and 8mm for 31G – Patient Interface
	Effective Gauge	34G	33G	31 and 32G
	Tip Con-figuration	Patient-side: Asymmetrical 3-bevel Cartridge-side: Bent (Eccentric)	Patient-side: Asymmetrical 3-bevel Cartridge-side: Bent (Eccentric)	Patient-side: 5-bevel
	Wall Type	Normal Wall (min. 0.089 mm) at distal tip (patient interface end)*	Normal Wall (min. 0.089 mm) at distal tip (patient interface end)	Extra Thin Wall
Sterilization		E-beam radiation (validated in accordance with ISO 11137-1 to achieve SAL 10^{-6})	Gamma radiation (validated in accordance with ISO 11137-1 to achieve SAL 10^{-6})	Gamma radiation

*The I.D. tapers like the O.D. of the device. The measurement point of the I.D. is the distal portion of the needle. The wall thickness of the cannula remains uniform throughout.

The proposed device and the predicate devices are classified under 21 CFR 880.5570, which states: "*A hypodermic single lumen needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.*"

The proposed device and the predicate devices use statements similar to the underlined portion of the excerpt from the regulation. The intended use of the devices are identical (the injection of fluids subcutaneously), and the indications only differ slightly between the proposed device and the predicates. The proposed device only differs from K123300 in that exenatide is not included. However, the Terumo device is otherwise identical in indications for use to the BD Pen Needle (K123300).

H. NON CLINICAL TESTS (807.92(b)(1))

Performance

Performance testing was conducted to ensure the safety and effectiveness of the Terumo® Pen Injector Needle 34 throughout the shelf life, verify conformity to the applicable parts of ISO standards, and demonstrate substantial equivalence to the predicate device. No new issues of safety and effectiveness were raised with the testing performed. The following performance tests were performed:

Test	Standard	Result
Surface finish	ISO 11608-2: 2012, ISO 9626: 1991, A1 2001	Meets standard.
Cleanliness		
Limits for acidity and alkalinity		
Dimensions		
Stiffness		
Resistance to breakage		
Resistance to corrosion		
Dimensions for needles	ISO 11608-2: 2012	Meets standard.
Determination of flow rate through the needle		
Bond between hub and needle tube		
Needle points		
Freedom from defects		
Lubrication		
Dislocation of measuring point at patient end		
Determination of functional compatibility with needle-based injection systems		
Ease of assembly and disassembly		
Sterility	ISO 11608-2: 2012, ISO 11137-1: 2006	Meets standard.

No deviations from recognized consensus ISO standards were identified in the testing to standards, except where the design of the needle resulted in a modified method or acceptance criterion.

Additionally, performance testing other than to the above ISO Standards was performed on the device. The device complies with the acceptance criteria established based on the predicates:

Performance Test	Results
Penetration resistance	Meets acceptance criteria
Seal film fitting strength	Meets acceptance criteria
Cap-hub fitting strength	Meets acceptance criteria

Performance testing demonstrates that the Terumo® Pen Injector Needle 34 conforms to the recognized consensus ISO standards, is substantially equivalent to the predicate devices, and is acceptable for clinical use throughout the shelf life.

Biocompatibility

In accordance with ISO 10993-1, the Terumo® Pen Injector Needle 34 is classified as: Externally Communicating Device, Blood Path Indirect, Short Term (<24 hours) Use, as the cannula is immediately withdrawn after injection into the body. The finished device's blood/body contacting parts were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" and *Draft Guidance for Industry and Food and Drug Administration Staff - Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing."* Screening tests were performed on accelerated aged devices to show that the biocompatibility is maintained throughout the shelf life of the product. Results of the testing demonstrate that the device is biocompatible throughout the shelf life of the product.

Non-aged, sterile, whole device
Cytotoxicity
Sensitization
Intracutaneous reactivity (acute)
Systemic toxicity (acute)
Pyrogenicity
Hemolysis
Physicochemical Profile (USP <661> and FTIR)

Accelerated-aged (5 years), sterile, whole device
Cytotoxicity
Hemolysis
Physicochemical Profile (USP <661> and FTIR)

Sterilization

The sterility of the device is assured using a sterilization method validated in accordance with ANSI/AAMI/ISO 11137 – Medical Devices – Validation and Routine Control of Radiation Sterilization. Though the sterilization method has changed from gamma irradiation to electron beam irradiation for the modified device, the Terumo® Pen Injector Needle 34 is sterilized to provide a Sterility Assurance Level (SAL) of 10^{-6}. Performance testing demonstrated that the device functionality is substantially equivalent, and biocompatibility testing confirmed that the device is still biocompatible.

Risk Analysis

A Product Risk Analysis was conducted in accordance with ISO 14971, taking into account the modifications to the previous device, and it was determined that any new risks were adequately captured and mitigated.

I. CLINICAL TESTS (807.92(b)(2))

This 510(k) does not include data from clinical tests.

J. CONCLUSION (807.92(b)(3))

In summary, the Terumo® Pen Injector Needle 34, subject of this 510(k), is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to:

1. K123300 BD 31G and 32G Extra Thin Wall (XTW) Pen Needles with PentaPoint™, manufactured by Becton, Dickinson and Company, New Jersey.
2. K052561 Terumo® Micro Tapered Pen Needle, manufactured by Kofu Factory of Terumo Corporation, Japan.

There is no significant difference that raises any new issues of safety and effectiveness.